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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,567	09/04/2003	Edward D. Daus	016325-008510US	7856
20350	7590	11/22/2005	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			TUCKER, ZACHARY C	
			ART UNIT	PAPER NUMBER
			1624	
DATE MAILED: 11/22/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/656,567

Applicant(s)

DAUGS, EDWARD D.

Examiner

Zachary C. Tucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Response to Amendment***

Claim 1 has been amended as requested by applicants in the correspondence filed 24 October 2005, which is in reply to the Requirement for Restriction mailed 19 July 2005.

***Amended Requirement for Restriction***

Regrettably, due to an error in the setting out of the Groups in the previously mailed Requirement for Restriction, this amended Requirement has been re-represented in the following:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16, drawn to a method for producing enantiomerically enriched  $\alpha$ -(phenoxy)phenylacetic acid compounds having the structure depicted in claim 1, classified in class/subclass 562/472.
- II. Claims 17-21, drawn to acid-base salts derived from an  $\alpha$ -(phenoxy)phenylacetic acid compound, classified in class 562/472.
- III. Claims 22 and 23, drawn to a process for enantioselectively producing an  $\alpha$ -(phenoxy)phenylacetate compound having the structure depicted in claim 22, and named in claim 23, classified in class/subclass 560/62.

The inventions are distinct, each from the other because:

Inventions I and II are related as processes of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process

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(MPEP § 806.05(f)). In the instant case the product made can be made by other materially different processes.

At page 1 of the instant specification, lines 19-25, US 6,262,118 (Luskey et al) is cited as being a reference wherein the cytochrome P450 enzyme inhibiting effect of halofenic acid - an  $\alpha$ -(phenoxy)phenylacetic acid embraced by the structural formulae in the instant claims - is described. The Luskey et al patent also teaches therapeutic application of enzymatically enriched halofenic acid, and how to make the compound.

In the paragraph bridging columns 15 and 16 of Luskey et al, it is taught that more than a few methods of making enantiomerically enriched forms of the compound are known. Mention is made of "conventional means known to and used by those of skill in the art," "simple crystallization and chromatographic resolution" and "enzymatic biocatalytic resolution." This serves to show that other methods of making the compounds of claim 21 are known.

It remains to be seen whether or not the instantly claimed method for producing an enantiomerically enriched  $\alpha$ -(phenoxy)phenylacetic acids as set forth in Group I is one of the "conventional means known to and used by those of ordinary skill in the art," mentioned in the Luskey et al patent. If so, then the acid-base salts according to claims 17-20 in Group I could be viewed as conventional.

Group III is a patentably distinct method of making a compound different than the compounds made by processes according to Group I claims. The showing of separate classification is evidence for distinctness of Group III from Groups I and II.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classification, restriction for examination purposes as indicated is proper.

Should applicant elect compounds of Group II (claims 17-21), and that subject matter proves to be allowable, then a method of making that compound, as set forth in Group I (claims 1-20), would be eligible for rejoinder. At such time of rejoinder, the requirement for restriction between Groups II and I would be withdrawn.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

### ***Drawings***

In the previous Office action, the drawings were objected to. The correspondence filed 24 October 2005, at page 9, states that replacement drawings sheets are enclosed. Those replacement drawings are not in the file. It is requested that applicants kindly supply the replacement drawings sheets.

### ***Conclusion***

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Tuesday-Thursday from 8:00am to 4:30pm or Monday from 6:00am to 1:30pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

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